18. (Original) The kit of claim 16, further comprising a device for subcutaneous, intravenous, or intrathecal deliver of the purine nucleoside or analog thereof.

19. (Original) The kit of claim 16, further comprising written instructions for the treatment of a central nervous system injury.

REMARKS

I. Status of the Application.

Claims 1 through 19 were pending in the original application (the "present application"). In a non-final Office Action dated October 5, 2005 (the "Office Action"), Examiner Howard Owens: (1) rejected Claims 1-3, 5-8, 10, 12, 13, and 14-19 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6,487,446 to Hill et al. (the "Hill Reference"); and (2) rejected Claims 1-19 under 35 U.S.C. § 103 as being obvious in light of the Hill Reference. In this response, the Applicants respectfully traverse the rejections of Claims 1-19, as the Hill Reference neither anticipates nor renders obvious any of the claims of the present application. Applicants respectfully request reconsideration of the pending claims in view of the following remarks.

II. Rejection of Claims 1-19 Under 35 U.S.C. § 102(b) Should Be Withdrawn.

A. The Hill Reference

The Hill Reference discloses a method for performing a medical procedure, such as a surgery, whereby spinal cord stimulation is used to control the beating of a heart or operation of lungs in order to control blood flow and pain during the surgery. Col. 1, lns. 9-14; Col. 1, lns. 43-50. In particular, the Hill Reference discloses use of a spinal cord stimulator configured to synchronize breathing along with vagus nerve stimulation to help control the patient's lungs and minimize unwanted heart motion. Col. 4, lns. 24-31. Additionally, the Hill Reference discloses the use of a nerve stimulator to stimulate the vagus nerve to produce asystole (slowing of the

heart beat) during surgery. Col. 4, lns. 60-65. Further disclosed is the optional stimulation of the carotid sinus nerve, the fat pad associated with the sinus-atrial ("SA") node, the fat pad associated with the atrial-ventricular ("AV") node, the junction of the AV node, or the junction of the AV node and the His bundle and/or Purkinje fibers to further control the heart rate. Col. 5, Ins 62-65. Therefore, the Hill Reference discloses the use of electrical stimulation of specific neural passages to control the physiological function of another organ—specifically the heart or lungs—during a surgical operation. Notably, the Hill Reference does not disclose electrical stimulation of damaged central nervous system tissue. In fact, the Hill Reference presupposes a functioning central nervous system to allow stimulation and control of the associated organ.

In addition, the Hill Reference also teaches the use of drugs or pharmaceutical formulations to help produce asystole (Col. 10, lns. 44-45), to help prevent oxidative damage caused during the surgical procedure (Col. 11, lns. 3-7), or to enhance an organ's reaction to stimulation of the sympathetic or parasympathetic nervous system, thereby allowing greater control of the organ during surgery (Col. 11, lns. 63-67). The Hill Reference discloses the use of acetylcholine or adenosine to inhibit reaction of the AV node and atria by inhibiting the flow of potassium ions across the cell membrane. Col. 14, Ins 14-36. However, the Hill Reference does not disclose the administration of a purine nucleoside to cause regeneration of nerve tissue in the central nervous system. Therefore, Applicants respectfully contend that the Hill Reference neither discloses nor makes obvious any of the claims in Applicant's present application.

B. The Rejection of Independent Claims 1, 13, 14, 15, and 16 Under 35 U.S.C. § 102(b) Should be Withdrawn

The Examiner has initially rejected Claims 1-19 under 35 U.S.C. § 102(b) as being anticipated by the Hill Reference, claiming that "Hill et al. anticipates the claims as it teaches the

administration of a purine (adenosine) in conjunction with electrical stimulation of the spinal cord to treat the spinal cord (col. 1-2), wherein the adenosine may be administered systemically, orally, or subcutaneously." As outlined above, and further detailed below, the Hill Reference does not disclose a treatment of a spinal cord injury, but rather discloses stimulation of a healthy nerve or spinal cord in an appropriate location to effect a physiological response such as slowing or controlling a patient's heart rate or lungs during a surgical procedure. Therefore, the present invention is not anticipated by Hill et al. because, (1) each and every element claimed in the present application is not disclosed in the Hill Reference, and (2) the disclosure in the Hill Reference is not enabling to practice the claims of the present application.

1. All Limitations of Applicant's Claims are Not Disclosed in the Hill Reference

In order to establish that a claim is anticipated by a reference, the reference must teach every element [or limitation] of the claim. MPEP § 2131. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987). Applicant respectfully asserts that the Examiner has failed to establish that all of the elements in the present application are set forth in the Hill reference, requiring a finding that the Hill Reference does not anticipate the claims of the present application.

a. Independent Claim 1 Is Not Anticipated

Independent Claim 1 claims:

> A method for treating a patient having a spinal cord injury, the method comprising:
> electrically stimulating the site of the spinal cord injury; and
> administering a purine nucleoside or analog thereof to the patient;
> wherein nerve function through said injured spinal cord is at least partially restored.

As discussed above, the Hill Reference does not disclose all of the claim elements comprising Independent Claim 1, as the Hill Reference does not disclose (1) electrically stimulating a site of a spinal cord injury, (2) administering a purine nucleoside or analog thereof to a patient having a spinal cord injury, or (3) at least partially restoring nerve function through a spinal cord. Instead, the Hill Reference merely discloses a method of controlling the heart and lungs by electrically stimulating the related nerves and areas of the spinal column to produce a physiological response.

Specifically, the Hill Reference does not disclose the limitation of "electrically stimulating the site of [a] spinal cord injury," as the Hill Reference assumes that the stimulated nervous tissue must be uninjured to produce the physiological response taught in its disclosure. Further, the Hill Reference does not disclose the administration of a "purine nucleoside or analog" to a patient having a spinal cord injury. Rather, the Hill Reference indicates that adenosine may be administered at the SA node to inhibit the flow of potassium ions across the cell membrane and help produce asystole of the heart. Col. 12, lns. 42-64. Finally, the Hill Reference does not disclose the restoration of nerve function nor the regeneration of nerve tissue, but rather discloses the control of heart rate and lung function. *See, e.g.* Col. 1, lns. 7-12. Therefore, as noted above, the Hill Reference cannot anticipate Independent Claim 1, as it does not disclose all of the limitations of Independent Claim 1. As such, Applicants respectfully request removal of the rejection to Applicants' Independent Claim 1 under 35 U.S.C. § 102.

b. Independent Claim 13 Is Not Anticipated

Independent Claim 13 claims:

> A method for treating a patient having a spinal cord injury, the method comprising:
> electrically stimulating the site of the spinal cord injury; and
> administering a purine nucleoside or analog thereof to the patient;

wherein nerve regeneration at the site of the spinal cord injury is stimulated.

The Hill Reference does not disclose all of the claim elements comprising Independent Claim 13, as the Hill Reference does not disclose (1) electrically stimulating a site of a spinal cord injury, (2) administering a purine nucleoside or analog thereof to a patient having a spinal cord injury, or (3) at least partially restoring nerve function through a spinal cord.

As noted above, the Hill Reference discloses a medical procedure in which "a spinal cord is stimulated to control at least one physiological function." Col. 1, lns 44-45. In particular, stimulation "to electrically manipulate cardiac rhythm by stimulation the vagus nerve" presupposes that the nerve stimulated is undamaged and operable. Col. 4, lns 59-61. If the stimulated nerve was damaged, stimulation thereof would not necessarily provide a physiological response, as the nerve would be unable to provide an impulse to the attached organ, such as the heart. Thus, the Hill Reference also does not disclose the electrical stimulation of a spinal cord injury, as no spinal cord injury is disclosed in the Hill Reference.

Further, the Hill Reference does not disclose the administration of a "purine nucleoside or analog" to a patient having a spinal cord injury, as claimed in the present application. Rather, the Hill Reference indicates that adenosine may be administered at the SA node to inhibit the flow of potassium ions across the cell membrane and help produce asystole of the heart. Col. 12, lns. 42-64. As noted above, the patient referred to in Independent Claim 13 is "a patient having a spinal cord injury. Since the Hill Reference does not reference treatment of a spinal cord injury, but rather presupposes that the patient must have a healthy nervous system to practice the method disclosed therein, the Hill Reference does not disclose the limitation of "administering a purine nucleoside or analog thereof to the patient [having a spinal cord injury]."

Finally, the Hill Reference does not disclose "nerve regeneration at the site of the spinal cord injury," but rather discloses the control of heart rate and lung function. *See, e.g.* Col. 1, lns. 7-12. Therefore, as noted above, the Hill Reference cannot anticipate Independent Claim 13, as it does not disclose all of the limitations of Independent Claim 13. As such, Applicants respectfully request removal of the rejection to Applicants' Independent Claim 13 under 35 U.S.C. § 102.

c. Independent Claim 14 Is Not Anticipated

Independent Claim 14 claims:

> A method for treating a patient having a spinal cord injury, the method comprising administering to the patient a purine nucleoside or analog thereof under conditions effective to restore nerve function through said injured spinal cord.

In the above discussion of Independent Claims 1 and 13, it was established that the Hill Reference does not make any disclosure related to administering a purine nucleoside or analog thereof to restore nerve function. Therefore, because the Hill Reference does not disclose administering a purine nucleoside or analog thereof under conditions effective to restore nerve function, the Hill Reference cannot anticipate Independent Claim 14. Applicants respectfully request removal of the rejection to Applicants' Independent Claim 14 under 35 U.S.C. § 102.

d. Independent Claim 15 Is Not Anticipated

Independent Claim 15 claims:

> A method for treating a patient having a spinal cord injury, the method comprising administering to the patient a purine nucleoside or analog thereof under conditions effective to stimulate nerve regeneration at the site of the spinal cord injury.

In the above discussion of Independent Claims 1, 13, and 14 it was established that the Hill Reference does not make any disclosure related to administering a purine nucleoside or analog

thereof to restore nerve function or nerve regeneration. Therefore, because the Hill Reference does not disclose administering a purine nucleoside or analog thereof under conditions effective to stimulate nerve regeneration at the site of the spinal cord injury, the Hill Reference cannot anticipate Independent Claim 15. Applicants respectfully request removal of the rejection to Applicants' Independent Claim 15 under 35 U.S.C. § 102.

e. Independent Claim 16 Is Not Anticipated

Independent Claim 16 claims:

> A kit for the treatment of a central nervous system injury, the kit comprising a means for the application of an electrical stimulation to the injury site and a purine nucleoside or analog thereof.

The Hill Reference does not make any disclosure related to "electrical stimulation to the [central nervous system] injury site." As discussed in the above sections, the Hill Reference presupposes a healthy nervous system in order to allow stimulation of nervous tissue to create a physiological response from an attached organ. Therefore, the Hill Reference cannot include the limitation of electrically stimulating a central nervous system injury site, as no such injury is disclosed or contemplated. Because the Hill Reference does not disclose a kit comprising a means for the application of an electrical stimulation to the injury site and a purine nucleoside or analog thereof, the Hill Reference cannot anticipate Independent Claim 16. Applicants respectfully request removal of the rejection to Applicants' Independent Claim 16 under 35 U.S.C. § 102.

2. The Hill Reference Contains No Enabling Disclosure Related to the Present Application

The Hill Reference is not enabling to practice any aspect of the claims of the present application. "In determining that quantum of prior art disclosure which is necessary to declare

an applicant's invention 'not novel' or 'anticipated' within section 102, the stated test is whether a reference contains an 'enabling disclosure'...." *In re Hoeksema*, 399 F.2d 269, 158 USPQ 596 (CCPA 1968). In addition, MPEP 2121.01 instructs that "[t]he disclosure in an assertedly anticipating reference must provide an enabling disclosure of the desired subject matter; mere naming or description of the subject matter is insufficient, if it cannot be produced without undue experimentation." MPEP 2121.01 *citing Elan Pharm., Inc. v. Mayo Foundation for Medical and Education Research*, 346 F.3d 1051, 1054 (Fed. Cir. 2003), emphasis added. Since the Hill Reference discloses only spinal stimulation of a healthy nervous system (particularly the vagus nerve or the spinal cord to elicit a physiological effect in the heart or lungs) and the use of adenosine to further cause asystole of the heart, there has been no enabling disclosure of any aspect of the inventions claimed by Applicants. As such, no one could be expected to practice a method of restoring nerve function or creating nerve regeneration by simply reading the Hill Reference, even with significant experimentation. Therefore, the Hill Reference cannot anticipate any of the claims of the present application.

C. The Rejection of the Remaining Claims Under 35 U.S.C. § 102(b) Should be Withdrawn

Remaining claims 2-12 depend from independent claim 1 and claims 17-19 depend from independent claim 16. Since neither independent claim 1 or independent claim 16 are anticipated by the Hill Reference, the remaining claims cannot be anticipated by the Hill Reference. Therefore, Applicants respectfully request reconsideration and withdrawal of the rejections of claims 2-12 and 17-19.

III. The Rejection of Claims Under 35 U.S.C. § 103(a) Should Be Withdrawn.

The Examiner's rejection of Claims 1-19 under 35 U.S.C. 103 with respect to the Hill Reference should be withdrawn, as the Hill Reference (1) does not disclose each element of claims in the present application, (2) discloses no motivation for treating a spinal cord injury, and (3) is non-analogous art. For these reasons, Applicants respectfully request the rejections be removed, and the claims of the present application be allowed.

A. The Examiner Has Failed to Make a Prima Facie Case of Obviousness

The rejection of Claims 1-19 under 35 U.S.C. 103 should be withdrawn because the Examiner has failed to make a *prima facie* case of obviousness. In order for the Examiner to establish a prima facie case of obviousness, there must be some suggestion or motivation to modify the references or combine the reference teachings, a reasonable likelihood of success in modifying the prior art, and the cited references must contain all of the limitations of the claims. MPEP §2143; *In re Rouffet*, 149 F.3d 1350 (Fed. Cir. 1998). As discussed in Section II above, the Hill Reference does not disclose each of the claimed limitations of the present application. In the Office Action the Examiner failed to identify any motivation in the prior art to modify the Hill reference. Therefore, the Examiner has failed to make a *prima facie* showing of obviousness, and the rejection should be withdrawn.

B. The Cited References Do Not Disclose All Elements of the Cited Claims

Even if the Examiner had cited a motivation to modify the Hill Reference, the modifications could not be combined to disclose all of the limitations of Claims 1-19. As discussed in Section II above, the Hill Reference does not disclose the limitation of electrically stimulating the site of a spinal cord injury, the administration of a purine nucleoside or analog to a patient having a spinal cord injury, nor does it disclose the restoration of nerve function or

regeneration of nerve tissue. Since none of these elements present in Claims 1-19 of the present invention are disclosed in the Hill Reference, the Examiner has failed to make a *prima facie* showing of obviousness.

C. The Hill Reference is Non-Analogous Art

As discussed above, Applicant respectfully brings to the Examiner's attention the fact that Hill et al. is non-analogous art. A reference is non-analogous art if: (i) the reference is not "within the field of the inventor's endeavor", and (ii) the reference is not reasonably pertinent to the particular problem with which the inventor was involved. *See In re Deminski*, 796 F.2d 436 (C.A.F.C. 1986).

With regard to the first prong of this test, the Hill Reference is not within the field of the present invention, as the Hill Reference relates to a method for modifying the beat pattern of a heart by stimulating the vagus nerve, spinal cord, or AV node to "allow blood flow to be controlled." Col. 1, lns. 13-14. The Hill Reference is not within the present invention's field of treatment of an injured spinal cord.

Second, the Hill Reference is not reasonably pertinent to the particular problem with which the present invention was involved. The purposes of both the invention and the prior art are important in determining whether the reference is reasonably pertinent to the problem the invention attempts to solve. *In re Deminski*, 796 F.2d 436 (C.A.F.C. 1986). If a reference disclosure is directed to a different purpose, the inventor will have little motivation or occasion to consider it. Id. The present invention is concerned with the treatment of injured nerves. Conversely, the Hill Reference is concerned with stimulating a healthy nervous system to effect a physiological response for another organ, such as modifying heart rate, during a surgical procedure. Thus, Applicant's disclosure and the Hill Reference are directed to different purposes

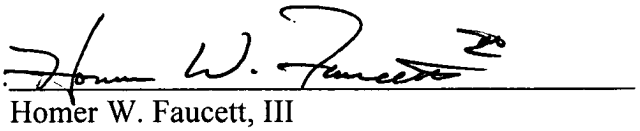
and attempt to solve totally different problems. Because of this, no motivation exists for one skilled in the art to even consider the Hill Reference when considering the problems solved by the present invention. The Hill Reference is simply not pertinent to the problem solved by the present invention. Therefore, because the Hill Reference (i) is not "within the field of the inventor's endeavor", and (ii) is not reasonably pertinent to the particular problem which the present invention solves, the Hill Reference is non-analogous prior art.

IV. Conclusion

For all the foregoing reasons, it is respectfully submitted that the Applicants have made a patentable contribution to the art and that this response places the above identified application in condition for allowance, or in the alternative this response places the application in a better form for appeal. Favorable reconsideration and allowance of this application is respectfully requested. Should the Examiner continue to find any of the Claims objectionable for any reason, the Examiner is respectfully requested to contact the undersigned for a telephone interview before taking further action. In the event the Applicants have inadvertently overlooked the need for an extension of time or payment of an additional fee, the Applicants conditionally petition therefor, and authorize any fee deficiency to be charged to deposit account 09-0007.

Respectfully submitted,

ICE MILLER

By: 

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